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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,936	11/17/1999	GUST H. BARDY	90980054-1	5202

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,936	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/8/05 (response)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,4,6-9,11,15,16 and 20-22* is/are allowed.

6)☒ Claim(s) *1,2,5,10,12-14,17-19 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims 1-2, 5, 10, 12 and 23 are withdrawn in view of the newly discovered reference(s) to Cohen ((5,269,301) and Ramsey III (5,928,270). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5, 10, 13-14 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (5,269,301).

With respect to claim 1, Cohen shows an atrial defibrillator comprising a portable, non-implantable housing; a pair of defibrillator pads operable to be applied to the outside of a patient's body; a shock generator disposed in the housing (16), coupled to the pads (standard skin patches anterior and posterior Col. 4, lines 64-65, see also Fig. 2G of U.S. Pat. No. 4,984,572 which is incorporated by reference and shows standard anterior and posterior skin patches), and operable to shock the patient via the pads (202, 204 of Fig. 2 of U.S. Pat. No. 4,984,572) in response to a shock command from an operator; and an analyzer disposed in the housing and operable to receive a cardiac signal from the patient, to determine from the signal whether the patient is experiencing atrial fibrillation, and to enable the shock generator if the patient is experiencing atrial fibrillation (Fig. 5B, steps 500-502, Fig. 5D steps 553-558, 613-614, Col. 4, lines 34-38, Col. 4, lines 49-54, Col. 7, lines 14-52, Col. 8, line 55-Col. 9, line 17).

Regarding claim 2, Cohen shows a control device (8) disposed in the housing.

With respect to claim 5, Cohen shows the analyzer is operable to receive the cardiac signal via the pads (standard skin patches anterior and posterior, Col. 4, lines 64-65). See also Fig. 2G of U.S. Pat. No. 4,984,572 that is incorporated by reference and shows standard anterior and posterior skin patches comprising sensing electrodes (212, 213)).

Regarding claim 10, Cohen further shows the analyzer is operable to determine from the cardiac signal whether the atrial fibrillation terminates after shock delivery (Fig, 5D, steps 555-558).

With respect to claim 13, Cohen shows a nonsurgical method of treating atrial fibrillation, comprising: transdermally receiving a cardiac signal from a patient by a transdermal electrode ((standard skin patches anterior and posterior, Col. 4, lines 64-65, and Fig. 2G of U.S. Pat. No. 4,984,572 which is incorporated by reference and shows standard anterior and posterior skin patches comprising sensing electrodes (212, 213)) determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; enabling a portable shock generator with a signal from the portable analyzer; receiving a shock command from an operator; and shocking the patient with the portable shock generator by means of the transdermal electrode (202, 204 of Fig. 2 of U.S. Pat. No. 4,984,572) in response to the shock command if the patient is experiencing atrial fibrillation (Fig. 5B, steps 500-502, Fig. 5D steps 553-558, 613-614, Col. 4, lines 34-38, Col. 4, lines 49-54, Col. 7, lines 14-52, Col. 8, line 55-Col. 9, line 17).

Regarding claim 18, Cohen further shows the analyzer is operable to determine from the cardiac signal whether the atrial fibrillation terminates after shock delivery (Fig, 5D, steps 555-558).

With respect to claim 14, Cohen shows a nonsurgical method of treating atrial fibrillation, comprising: receiving a cardiac signal from a patient via defibrillation pads ((standard skin patches anterior and posterior, Col. 4, lines 64-65, and Fig. 2G of U.S. Pat. No. 4,984,572 which is incorporated by reference and shows standard anterior and posterior skin patches comprising sensing electrodes (212, 213)) determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; informing the patient by means of the analyzer that the patient is experiencing atrial fibrillation (via display 9); receiving a shock command from an operator; and shocking the patient with the portable shock generator by means of the defibrillator pads (202, 204 of Fig. 2G of U.S. Pat. No. 4,984,572) in response to the shock command if the patient is experiencing atrial fibrillation (Fig. 5B, steps 500-502, Fig. 5D steps 553-558, 613-614, Col. 4, lines 34-38, Col. 4, lines 49-54, Col. 7, lines 14-52, Col. 8, line 55-Col. 9, line 17).

Assuming arguendo that the method of Cohen does not inform the patient that the patient is experiencing atrial fibrillation, the examiner points out that the display (9) that is disclosed as being utilized for informing a doctor that the patient is experiencing atrial fibrillation can also inform the patient when the display is placed near the patient's bedside and the patient is looking at the display near his/her bedside. (See Fig. 2G of U.S. Pat. No. 4,984,572).

With respect to claim 17, Cohen shows a nonsurgical method of treating atrial fibrillation, comprising: transdermally receiving a cardiac signal from a patient ((via standard

skin patches anterior and posterior, Col. 4, lines 64-65, and Fig. 2G of U.S. Pat. No. 4,984,572 which is incorporated by reference and shows standard anterior and posterior skin patches comprising sensing electrodes (212, 213)) determining from the signal with a portable external analyzer whether the patient is experiencing atrial fibrillation; applying a shock enable signal to a portable shock generator external to the patient if the patient is experiencing atrial fibrillation; where the determining comprises determining the patient's heart rate and determining the patient is not in atrial fibrillation if the heart rate is outside a predetermined range (via determination that the heart rate is within the normal range or by determining that it is low - below 60 bpm) (Fig. 5B, steps 500-502, Fig. 5D steps 553-558, 613-614, Col. 4, line 34-Col. 5, lines 13, Col. 7, lines 14-52, Col. 8, line 55-Col. 9, line 17).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (5,269,301) in view of Druz (3,442,269). Cohen is as explained before. Although Cohen fails to teach or suggest shocking the patient during the rising edge of an R-wave in the cardiac signal, attention is directed to Druz which teaches shocking the patient during the rising edge of an R-wave in the cardiac signal (Col. 6. lines 32-62). Shocking the patient in "synch" with the R-wave avoids the possibility of shocking the heart during its vulnerable period and thus inducing ventricular fibrillation. Therefore it would have been obvious to one with ordinary skill in the art

at the time the invention was made to modify the method of Cohen with the additional step of shocking the patient during the rising edge of an R-wave in the cardiac signal in order to avoid shocking the heart during its vulnerable period and inducing ventricular fibrillation.

6. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (5,269,301) in view of Ramsey III. Cohen is as explained before. Although Cohen fails to show utilizing a multiphasic waveform to shock the patient, attention is directed to Ramsey which teaches it is well known in the art to treat atrial fibrillation with bi-phasic and multi-phasic waveforms (Col. 3, lines 46-63, Col. 6, lines 35-38, Figs. 3-5). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Cohen with a shock generator that is operable to shock the patient with a multi-phasic waveform, since Ramsey teaches it is well known to treat atrial fibrillation with bi-phasic and multi-phasic defibrillation pulses.

Allowable Subject Matter

7. Claims 3-4, 6-9, 11, 15-16, and 20-22 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

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